DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-22 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shalaby (US 6,413,539).

6. Regarding Claim 1, Shalaby teaches hydrogel-forming polyester copolymers (col. 6, lines 33-37). Said copolymer is used for controlled release of a biologically active agent/drug for modulating cellular events such as wound healing and tissue regeneration, as well as for therapeutic treatment of a variety of diseases (col. 6, lines 45-53).

7. The copolymers comprise a base component designated “Component A”. Component A comprises molecular chains having a hydrophilic block ”Y” and a hydrophobic polyester block “X”. Hydrophobic block X (corresponding to claimed pre-polymer A) comprises a polyester formed by grafting a glycolide, lactide, caprolactone, p-dioxanone, trimethylene carbonate, or combinations thereof, onto the end group of a hydrophilic polymer block Y (corresponding to the claimed pre-polymer B) such as polyoxyethylene (equivalent to PEG) or poly(oxyethylene-b-oxypropylene) (equivalent to PEG-PPG), interlinked with oxalate or succinate functionalities (multi-functional chain extenders) (col. 10, lines 34-51).

8. Component A is preferably a liquid at room temperature, being practically amorphous (with less than 5% crystallinity), with a Tg of less than 25°C (col. 11, lines 1-8). Shalaby is silent with respect to the degree of amorphousness at human body temperature (i.e. ~37°C). However, Shalaby's copolymer is formed from components which are compositionally identical to the claims. Additionally, said copolymer has a Tg of less than 25°C and possesses less than 5% crystallinity at room temperature. As such, reasonable basis exists to believe that the copolymer will be completely amorphous at human body temperature, 12°C higher than the copolymer's Tg. Since the PTO cannot conduct experiments, the burden of proof is shifted to the Applicant to establish an unobvious difference. In re Fitzgerald, 619 F.2d. 67, 205 USPQ 594 (CCPA 1980). See MPEP 2112-2112.02. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

9. Shalaby as set forth above reads on all elements of Claims 1-6, 13, 14, 17, 18, and 22.

10. Claim 7 defines claimed pre-polymer A by a product-by-process limitation. Although Shalaby does not disclose a reaction product of a cyclic monomer with a non-cyclic initiator selected from the group consisting of diols, dicarboxylic acids, and hydroxycarboxylic acids, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product

was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) . Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

11. In the present case, Shalaby's hydrophobic block X may be a polymer of glycolide or lactide as stated above. A polymer formed by initiating polymerization of lactide (a cyclic monomer) with a lactic acid monomer (a hydroxycarboxylic acid), for example, is chemically indistinguishable from a polymer containing only lactic acid repeating units formed through other means. The same is true for polymers of glycolide initiated by glycolic acid.

12. Therefore, absent evidence of criticality regarding the presently claimed process and given that Shalaby's copolymers of glycolide, lactide, or caprolactone meets the requirements of the claimed composition, Shalaby clearly meet the requirements of present Claims 7, 8, and 12.

13. Regarding Claim 9, Shalaby suggests the use of combinations of monomers such as glycolide, lactide, and/or caprolactone (col. 10, lines 41-44). Thus, it would have been obvious to follow this suggestion and incorporate more than one of these monomers into block X.

14. Regarding Claims 10 and 11, as stated above, Shalaby teaches the sue of combinations of monomers which include glycolide, caprolactone, and lactide. It would have been obvious to combine glycolide with either caprolactone (Claim 10) or lactide

(Claim 11), as the monomers are expressly taught as being suitable for this purpose. Shalaby is silent with respect to a ratio in which to combine these monomers. However, when faced with a combination of equivalent elements, one of ordinary skill in the art would be motivated by common sense to select a 1:1 ratio absent evidence of unexpected results. Case law holds that "[h]aving established that this knowledge was in the art, the examiner could then properly rely…on a conclusion of obviousness, 'from common knowledge and common sense of the person of ordinary skill in the art within any specific hint or suggestion in a particular reference." *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

15. Regarding Claim 15, Shalaby teaches the use of PEG with a molecular weight of 400-900 (col. 12, lines 49-51). This range falls within the claimed range of 150-4000. Shalaby additionally teaches the use of PEG as an initiator for a mixture of glycolide and lactide (col. 10, lines 57-60).

16. Regarding Claim 16, the claims do not specify the identity of pre-polymer A. Thus, Shalaby's PEG block may be cited as reading on the pre-polymer A of Claim 1. As stated above, Shalaby teaches the use of PEG with a molecular weight of 400-900 (col. 12, lines 49-51). This range falls within the claimed range of 300-30000.

17. Regarding Claim 19, Shalaby does not teach the molecular weight of hydrophobic polyester block X as described above, in this case corresponding to the claimed pre-polymer B. However, one of ordinary skill in the art will at once recognize that the molecular weight of each block in Shalaby's copolymer will affect the inherent viscosity and Tg of the final product. As such, molecular weight of block X is a result-

effective variable. Thus, it would have been obvious to one of ordinary skill in the art to employ a block X having the optimum or workable molecular weight corresponding to the range recited in the claims, with a reasonable expectation of successfully obtaining desired inherent viscosity and Tg of the final product. See MPEP 2144.05.

18. Regarding Claim 20, Shalaby teaches a block copolymer with a ratio of ether blocks/ester blocks of 20-49/80-51. Thus, Shalaby suggests the use of ester blocks in the amount of 51-80%. This range falls within the claimed range of 10-90%.

19. Regarding Claim 21, Shalaby teaches an inherent viscosity ranging from 0.03-0.80 dL/g (col. 11, lines 1-4). This falls within the claimed range of 0.1-6 dL/g.

20. Regarding Claim 42, Shalaby teaches biologically active agents/drugs such as antibiotics, peptides, proteins, anti-anflammatory agents, anticancer agents, immunosuppressive agents, anesthetics, lipopolysaccharides, cisplatin (chemotherapeutic agent), and tissue growth factors (col. 11, lines 33-45).

21. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby as applied to Claims 1 and 22 above, further in view of Cohn et al (WO 03/080119; US 7,425,322 referred to herein as the US equivalent).

22. As stated above, Shalaby teaches block copolymers interlinked with oxalate (derived from oxalic acid) or succinate (derived from succinic acid) functionalities (col. 10, lines 50-51). Shalaby does not teach the use of a diisocyanate linker.

23. In the same field of endeavor, Cohn teaches responsive biomedical composites (Title). In a preferred embodiment, the composites comprise a block copolymer wherein

the blocks are connected via a chain extender. Exemplary chain extenders include aliphatic dicarboxylic acids and diisocyanates (col. 8, lines 21-34). Thus, Cohn demonstrates that when forming block copolymers for biomedical applications, aliphatic dicarboxylic acids and diisocyanates are equivalents suitable for the same purpose.

24. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shalaby in view of Cohn to substitute oxalate or succinate functionalities with diisocyanate functionalities, as the two are demonstrated by Cohn as being equivalents suitable for the same purpose. Modification in this way reads on Claim 23.

Response to Arguments

25. Applicant's arguments with respect to claims 1-23 and 42 have been considered but are moot in view of the new grounds of rejection.

Conclusion

26. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

27. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSJ

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